

Applicants hereby gratefully acknowledge the telephone conference with Examiner Eleni M. Mantis Mercader, on March 11, 2003, wherein Applicants' attorney, David J. Dykeman, and Examiner Mercader discussed the Office Action mailed on December 18, 2002 and the cited prior art.

On March 11, 2003, Attorney Dykeman and Examiner Mercader discussed the Information Disclosure Statement ("IDS") filed on August 10, 2001 that was not initialized and not included with the Office Action. Examiner Mercader confirmed the IDS from August 10, 2001 was not initialized and agreed to review the IDS filed on August 10, 2001, initial the IDS, and send the initialized IDS to Applicants.

On March 11, 2003, Attorney Dykeman and Examiner Mercader also discussed a Preliminary Amendment filed on December 11, 2002 with additional claims 63-82 which was not made of record. Attorney Dykeman confirmed receipt of a return postcard acknowledging receipt of the Preliminary Amendment (stamped December 11, 2002 by U.S. Patent and Trademark Office) and verified the \$264 check was cashed by the U.S. Patent and Trademark Office. Attorney Dykeman and Examiner Mercader agreed that upon receipt of a fax copy of the Preliminary Amendment filed December 11, 2002 along with a copy of the stamped postcard, the Preliminary Amendment would be entered. On March 11, 2003, Applicants faxed the copy of the Preliminary Amendment to Examiner Mercader. Thus, Applicants respectfully request entry of the Preliminary Amendment containing claims 63-82.

With the Preliminary Amendment originally filed on December 11, 2002, Applicants added new claims 63-82 which are of similar scope to Group II (claims 17-28, 49-62). As discussed with Examiner Mercader, Applicants request new claims 63-82 be added to Group II. Thus, Applicants hereby confirm election of **Group II (Claims 17-28, 49-62 and new claims 63-82)** for prosecution on the merits, with traverse.

The Office Action rejected claims 17-24, 26-28, 49-58 and 60-62 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,846,790 to Hornlein, et al. ("the Horlein et al. '790 patent"). Also, the Office Action rejected claims 25 and 59 under 35 U.S.C. § 103(a) as being unpatentable over Hornlein et al. '790 patent in view of U.S. Patent No. 5,193,525 to Silverstein, et al. ("the Silverstein et al. '525 patent"). Also, the Office Action rejected claims

17-24, 26-28, 49-58 and 60-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 9 of co-pending Application No. 09/784,619.

The Office action rejected claims 17-24, 26-28, 49-58 and 60-62 under 35 U.S.C. 102(b) as being anticipated by Hornlein et al. '790 patent. The Office Action stated on page 5:

Hornlein et al. '790 teach all the features of the instant invention including an ultrasonic treatment apparatus having:

An ultrasonic probe having an ultrasonic tip, the ultrasonic probe including at least one channel on an outer surface of the ultrasonic probe, the at least one channel extending from the proximal end of the ultrasonic probe to a location adjacent the ultrasonic probe (see Figure 1; col. 6, lines 44-66; and also see Figures 4A and 4B; and col. 8, lines 9-42). The probe therefore includes a number of channels one of which spirals around the outer surface of the ultrasonic probe (see Figure 4A and 5 and in particular element 76). The ultrasonic probe includes an irrigation passage (in Figure 5 see element 89 and in col. 8, lines 51-60). The sheath of the probe, element 60 is depicted in Figure 3. The axial arrangement of the parts and their interconnections are depicted in Figures 3, 4A and 4B.

The Office Action stated "claims 17-24, 26-28, 49-58 and 60-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hornlein et al. '790." For this Amendment, Applicants assume that claims 60-62 are rejected and the rejection of 60-49 is a typographical error.

To anticipate a claim, the reference must teach every element of the claim. M.P.E.P. 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P. 2131. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); M.P.E.P. 2131.

With this Amendment, Applicants have amended independent claims 17, 49, 61, 63 and 73 to claim an ultrasonic treatment apparatus comprising an ultrasonic probe and **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.** Hornlein et al. does NOT disclose or suggest an ultrasonic treatment

apparatus comprising an ultrasonic probe and **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.**

Instead, Hornlein et al. discloses a device where aspiration occurs through a single aspiration passage. As such, Applicants respectfully request reconsideration and allowance of pending claims 17-28 and 49-82.

The amended claims recite an ultrasonic probe and **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.** With this Amendment, no new matter is added. Support for these Amendments can be found in at least FIG. 11 and the following passages from Applicants' specification:

Another advantage of the **use of channels for aspiration** is that they are easier to contact with the materials to be aspirated and to remain clear than an internal passage for aspiration, and they also are **less prone to blockage than an internal aspiration passage.** (Applicant Specification; P. 8, Para. 1) (Emphasis added)

One way in which the present invention allows the cross-sectional profile of the probe to be minimized is by allowing **aspiration to occur through grooves or channels on the outer surface of the probe.** In this way, there is no need for an additional tubular aspiration sheath to be inserted into the urethra, to thereby provide a aspirating path. (Applicant Specification; P. 8, Para. 1) (Emphasis added)

Furthermore, because the **grooves or passages are located on the outside of the probe,** they are less likely to become obstructed or clogged, and furthermore, they are much easier to clean than internal aspiration passages. (Applicant Specification; P. 17, Para. 1) (Emphasis added)

First, the use of **grooves or channels** eliminates the need for an additional sheath surrounding the probe **to create an aspiration passage.** As a result, the cross-sectional profile of the instrument can be reduced, thereby reducing residual tissue damage and edema. Furthermore, the grooves or channels allow an aspiration sheath to be located outside of the passage or lumen to the treated area - such as the urethra. (Applicant Specification; P. 16, Para. 3) (Emphasis added)

Applicants have amended independent claims 17, 49, 61, 63 and 73 to claim an ultrasonic treatment apparatus comprising an ultrasonic probe and **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration**

occurs through the at least one aspiration channel along the length of the ultrasonic probe. As such, Applicants respectfully request reconsideration and allowance of pending claims 17-28 and 49-82.

U.S. Patent No. 4,846,790 to Hornlein et al. discloses an ultrasonic surgical aspiration system with an aspiration passage and the aspiration tube lies along the body of the handle assembly. Hornlein et al. discloses:

Aspiration occurs from the operative site **through an aspiration passage** to the aspiration port and through the **aspiration tubing** to aspirate surgically-excised particles. (Hornlein et al. '790 patent; Col. 2, Lines 35-37)

As shown in FIGS. 4A and 5, after connecting the connector 71 as described, **the aspiration tube 76 lies along the body of the handle assembly 31** and is secured thereon by resilient bands 76A similar to the current manner. (Hornlein et al. '790 patent; Col. 8, Lines 43-47)

An important feature of the invention, as best seen in FIGS. 4A and 4B and in detail in FIGS. 24-26, involves the use of an aspiration tubulation connector 71 for connecting **the aspiration tubing 76** to the aspiration port 37 on the tip 34 within the chamber 39 on the interior of the assembly 30. (Hornlein et al. '790 patent; Col. 8, Lines 9-14)

As discussed above, Hornlein et al. does NOT disclose **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.** Thus, Hornlein et al. does NOT anticipate or suggest the Applicants' claimed invention. As such, Applicants respectfully request reconsideration and allowance of pending claims 17-28 and 49-82.

The Office Action rejected claims 25 and 59 under 35 U.S.C. 103(a) as being unpatentable over Hornlein et al. '790 patent in view of U.S. Patent No. 5,193,525 to Silverstein et al. The Office Action stated on page 6:

Hornlein et al. '790 do not teach a fiberoptic endoscope having channels for insertion of treating tools including ultrasound therapeutic probe.

Silverstein et al. '525 teaches a fiberoptic endoscope having channels for insertion of treating tools including ultrasound therapeutic probe (see col. 8, lines 24-38; col. 12, lines 50-68; and col. 13, lines 1-2).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Hornlein et al. '790 and included the teaching of Silverstein et al. '525 in inserting a fiberoptic through one of the channels in order to image the area of interest for monitoring purposes.

As discussed above, Applicants have amended independent claims 17, 49, 61, 63 and 73 to claim an ultrasonic treatment apparatus comprising an ultrasonic probe and **an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.** As such, Applicants respectfully request reconsideration and allowance of pending claims 17-28 and 49-82.

“Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” M.P.E.P. 2143.01. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). See also *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992); M.P.E.P. 2143.01.

As discussed above, Hornlein et al. does NOT disclose an ultrasonic treatment apparatus comprising an ultrasonic probe and an **at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.** The additional reference of Silverstein et al. does not cure or offer a suggestion on how to overcome the deficiencies of Hornlein et al. Silverstein et al. discloses an antiglare tip for the sheath of an endoscope to prevent glare in an image viewer. Silverstein et al. does NOT disclose or suggest an ultrasonic treatment apparatus comprising an ultrasonic probe and an **at least one aspiration**

channel recessed along the length of an outer surface of the ultrasonic probe wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe. As such Silverstein et al. does not cure or offer a suggestion on how to overcome the deficiencies of Hornlein et al. Applicants respectfully request withdrawal of the obvious rejection to claims 25 and 59, and reconsideration and allowance of pending claims 17-28 and 49-82.

The Office Action rejected claims 17-24, 26-28, 49-58 and 60-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,8 and 9 of co-pending Application No. 09/784,619. The Office Action stated on page 4:

Claims 17-24, 26-28, 49-58 and 60-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 9 of co-pending Application No. 09/784,619. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one skilled in the art based on the knowledge of skilled artisans to have used the ultrasonic probe with vibrations in its longitudinal axis as this is well known in using ultrasonic end-effectors in surgical procedures.

Regarding double patenting between co-pending applications – provisional rejections, M.P.E.P. §804(I)(B) states:

If the ‘provisional’ double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the ‘provisional’ double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. (M.P.E.P. §804(I)(B); Page 800-19)

As such, Applicants respectfully traverse the provisional double patenting rejection.

In summary, the cited prior art references, alone or in combination, do not anticipate, suggest, or make obvious Applicants’ claimed invention in pending claims 17-28, 49-82 and the rejections in the Office Action should accordingly be withdrawn. Reconsideration and allowance of pending claims 17-28 and 49-82 is respectfully requested.

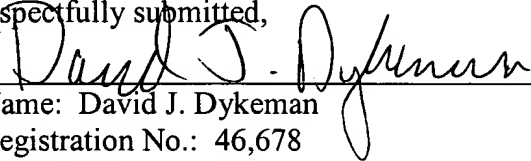
With this Amendment, Applicants have made an earnest effort to respond to all issues raised in the Office Action of December 18, 2002, and to place all claims presented in condition for allowance. No amendment made was for the purpose of narrowing the scope of any claim,

unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

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Respectfully submitted,



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MARKED-UP VERSION OF AMENDMENTS:

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

Please amend claims 17, 49, 61, 63 and 73 as follows:

Do not
exist!

17. (Amended)

An ultrasonic treatment apparatus comprising:

an ultrasonic probe having an ultrasonic tip; [and]

an aspiration sheath surrounding at least a portion of a length of the ultrasonic probe, the aspiration sheath forming at a distal end an aspiration port, the aspiration sheath being movable axially relative to the ultrasonic probe[.]; and

an at least one aspiration channel recessed along the length of an outer surface of the ultrasonic probe, wherein aspiration occurs through the at least one aspiration channel along the length of the ultrasonic probe.

49. (Amended)

An ultrasonic treatment apparatus comprising:

an ultrasonic probe having an ultrasonic tip, the ultrasonic probe including an at least one channel [on] recessed along a length of an outer surface of the ultrasonic probe, the at least one channel extending from a proximal end of the ultrasonic probe to a location adjacent the ultrasonic tip[.]

wherein aspiration occurs through the at least one channel along the length of the ultrasonic probe.

61. (Amended)

An ultrasonic probe comprising[;]:

an elongate shaft [with] having a longitudinal axis with a recessed portion[; the recessed portion] bounded at one end with a planar surface; and [.]

A³

an at least one aspiration channel recessed along an outer surface of the longitudinal axis of the elongate shaft, wherein aspiration occurs through the at least one aspiration channel along the longitudinal axis of the elongate shaft.

63. (Amended)

An ultrasonic medical device comprising:

a probe having a distal end, a proximal end and an axial length therebetween; [and]

a diameter of the probe that is tapered from the [distal] proximal end of the probe to the [proximal] distal end of the probe[.]; and

an at least one aspiration channel recessed along an outer surface of the axial length of the probe,

A⁴

wherein the probe can support a transverse ultrasonic vibration along at least a portion of the axial length of the probe.

73. (Amended)

A medical device comprising:

a flexible probe having a distal end, a proximal end and an axial length therebetween; [and]

a probe tip extending from the distal end of the probe[.]; and

an at least one aspiration channel recessed along an outer surface of the axial length of the flexible probe,

A⁵

wherein the flexible probe is capable of flexing to support a transverse ultrasonic vibration along at least a portion of the axial length of the flexible probe.